

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**UNITED STATES OF AMERICA**

**Plaintiff,**

**V.**

BARRY J. CADDEN, et al.

**Defendants.**

**Case No. 14-CR-10363-RGS**

**ORAL ARGUMENT REQUESTED**

**DEFENDANT KATHY S. CHIN'S**  
**MOTION *IN LIMINE* TO EXCLUDE EVIDENCE**  
**OF UNCHARGED SHIPMENTS**

The Defendant Kathy S. Chin moves for an order *in limine* prohibiting evidence of or reference in the arguments of counsel to uncharged drug shipments from NECC with which she allegedly had some involvement. Although she is only charged in the indictment with FDCA violations in connection four discrete drug shipments, the government apparently intends to introduce evidence of 2000+ additional drug shipment in it case in chief against her.

Kathy Chin is not charged in any conspiracy or RICO count and as a low level employee of the corporation cannot be held vicariously liable for the misdeeds - if any - of her coworkers. The government does not allege with respect to any of the 2000+ uncharged shipments that she failed to do her job which was to make sure that the correct medication was sent to the correct facility. Thus evidence of these uncharged shipments is irrelevant, misleading, unduly prejudicial and a waste of judicial resources and should be excluded.

Alternatively, the defendant requests that the court order the government to provide a list of exhibits and uncharged shipments it intends to offer against her at trial and order a postponement of the trial and severance from her codefendants to allow her to research and prepare to defend against this large number of additional shipments which dwarf the four shipments that form the basis of the four counts against her in this indictment.

## **BACKGROUND**

### **Charges against Kathy Chin – 4 shipments**

The government has charged Kathy Chin as one of 14 defendants in this case. Ms. Chin is charged for her role as an employee pharmacist at New England Compounding Center (“NECC”). The government alleges that NECC improperly manufactured and sold tainted drugs resulting in patient deaths. The government charges that NECC intentionally avoided FDA oversight by falsely claiming to be a pharmacy and not a drug manufacturing facility. Ms. Chin is alleged to have intentionally dispensed prescription drugs without valid individual prescriptions in connection with four shipments of medications. (Counts 104-107)

Specifically, in connection with the four orders that are the subject of the four counts against Ms. Chin, the government claims that the Prescription Order Forms contained obviously fake patient names and that NECC and Ms. Chin knowingly shipped the drugs anyways. Ms. Chin's job was to check that the drug that was ordered was being sent to the correct facility and she filled out a check list for each order verifying that information. Ms. Chin had no responsibility for checking prescriptions or patient names. That function was performed by other NECC employees in the confirming department under the direct supervision of Head Pharmacist and Manager of Record Barry Cadden. Ms. Chin was a low level employee in the shipping department and had no supervisory role at the company.

The government does not allege that the drugs that were shipped pursuant to the four charged orders were tainted, improperly prepared or tested or caused harm to anyone at all. Nor does the government claim that Chin ever failed to do her job, ensuring that the right drugs went to the right facility.

**Government Ex. 595: Summary Exhibit of Patient Names Discrepancies – 2000 uncharged shipments against Kathy Chin**

On its exhibit list the government has disclosed a new summary exhibit that was not offered at either of the two prior trials of this indictment. Government Exhibit 595 entitled “Summary Exhibit of Patient Names Discrepancies” is a 95 page spreadsheet containing (approximately) 4,500 shipments only 12 of which are charged in the indictment. The first two pages of the exhibit are entitled “Fake Name Shipments” and begins with 12 shipments that form the basis of 12 charges against defendants Chin (4 counts), Thomas (2 counts) and Stepanets (7 counts, one with Thomas) and then adds 69 uncharged shipments. The next eight pages of the exhibit are entitled “Doctor/Employee Name Shipments” and contains (approximately) an additional 300 uncharged shipments. The last 85 pages of the document entitled “No Name Shipments,” comprising almost entirely shipments to large well-known hospitals, contains (approximately) an additional 4,000 uncharged shipments.

The spreadsheet contains a column entitled “NECC pharmacist check” which lists the name of the pharmacist who allegedly signed the form verifying that the correct drugs were going to the correct facility. Kathy Chin's name appears next to the four shipments with which she is charged and next to approximately 2,000 additional shipments with which she is not charged. By including this column, the government wrongly implies that the checking pharmacist had some responsibility for checking names or prescriptions. That function was instead performed by the NECC confirming department under the direct supervision of Barry Cadden.

Notably the government does not include in its summary a column for the NECC confirmer, in most cases government witnesses Bel Carvalho or Steve Sanda. By way of comparison the government did include a column for NECC confirmer in Government Exhibit 824, Summary of Alleged Contaminated Methylprednisolone Shipments. The government summary also fails to include columns for the dispensing pharmacist, in most cases Barry Cadden, or the prescribing physician, both of whom – unlike Kathy Chin -- had direct responsibility for ensuring that the shipments were related to valid prescriptions.

The government does not identify the 2000 new shipments allegedly checked by Kathy Chin by Bates number so it will take substantial effort to locate the documents related to each shipment if in fact that can be done at all given the state of the discovery, the varying levels of searchability and the fact the the checking pharmacist's signature or initials is handwritten and therefore not searchable.

#### **Other Government Summary Exhibits**

The government exhibit list includes a number of other summary charts which purport to accuse Kathy Chin of impropriety in connection with numerous other uncharged shipments:

Government Exhibit 824: Summary of Alleged Contaminated Methylprednisolone Shipments – 50 uncharged shipments against Kathy Chin.

This seven page spreadsheet of approximately 185 allegedly contaminated shipments contains a column for “NECC pharmacist check” in which Kathy Chin's name appears against approximately 50 shipments. Kathy Chin is not charged in any count of the indictment with having anything to do with allegedly contaminated shipments. None of the shipments on this summary sheet which contain her name are the subject of any charges against her. The summary suggests that as checking pharmacist Kathy Chin had something to do with the contaminated shipments or could have known or prevented the contaminated shipments from being sent out.

There is no evidence at all that Kathy Chin or any checking pharmacist had any way of knowing that any shipment was contaminated or could have prevented its being sent out.

Government Exhibit 826: Summary of Unlicensed Tech Shipments - 150 uncharged shipments against Kathy Chin.

This six page spreadsheet apparently lists the shipments (approximately 250) of drugs prepared by an unlicensed pharmacy technician at NECC. The summary contains a column entitled "Pharmacist – Logged Formula Worksheet" under which Kathy Chin's name is listed next to approximately 150 shipments. Kathy Chin is not charged in the indictment with wrongdoing with respect to any of the shipments. The summary sheet wrongly suggests that the pharmacist who signed the Logged Formula Worksheet had some responsibility for the checking that drugs were prepared by licensed technicians.

Government Exhibit 827: Summary of Alleged Expired Shipments – unknown number of uncharged shipments against Kathy Chin.

This four page spreadsheet lists approximately 120 shipments which according to the government contained expired ingredients. The summary lists the Logged Formula Worksheet ("LFW") Pharmacist - often Glenn Chin - but it is not clear if that refers to the pharmacist who made the medication or the checking pharmacist and, if not, who the checking pharmacist is. There are no Bates numbers provided in the summary and counsel has not been able to locate the LFWs among the discovery or the Catalyst database. Moreover, the checking pharmacist's signature is handwritten and therefore not searchable in any event. Thus Kathy Chin has no way of knowing which if any of the shipments referenced in this summary will be cited by the government as evidence against her or if so why.

**Other Government Exhibits listing uncharged shipments against Kathy Chin – possibly hundreds of uncharged shipments against Kathy Chin**

Before the Cadden trial, the government provided a preliminary exhibit list broken out by defendant. There Kathy Chin learned for the first time that the government intended to offer into

evidence against her over 100 Logged Formula Worksheets signed by her for shipments for which she had not been charged.

The current exhibit list provided by the government is not broken out by defendant. By letter dated August 28, 2018, the defendants jointly requested that the government inform each defendant of the exhibits the government intends to introduce against him or her. By letter dated September 7, 2018, the government denied that request on that grounds that all of the proffered evidence is admissible against defendants charged in the conspiracy counts. The government gave no rationale for denying the request as to Kathy Chin who is not charged in any RICO or conspiracy count. In addition, the government has provided only a generic 404b disclosure which does not comply with FRE 404b's notice requirement and has not responded to the defendants' request for specific notice for each defendant. Therefore the defendant must search the entire list of 915 exhibits, many of which are multi page, to locate any reference to Kathy Chin on the assumption that the government will seek to use the document against her.

Moreover, it appears that the government has both subtracted from and added to its myriad uncharged allegations of wrongdoing by Kathy Chin completely undermining any reasonable effort to prepare for trial. For example, after quickly reviewing some 100 logged formula worksheets in the current exhibit list, it appears that there are only a handful listed that are allegedly signed by Kathy Chin. Most of the 100 LFWs included on the preliminary exhibit - and which the defendant then spent time reviewing - are no longer listed as government exhibits. Instead, as discussed above, the government has offered new Summary Exhibit 595 charging Ms. Chin with wrongdoing in 2000 additional drug shipments.

With those caveats, we have so far found many other exhibits that have logged formula worksheets or pharmacist verification forms that may have been signed by Kathy Chin for shipments unrelated to the counts against Kathy Chin. None of these documents are attributed to

Kathy Chin on the government's exhibit list. Ms. Chin's name or signature can only be determined by going page by page through the 915 government exhibits, many of which contains hundreds of pages each. Ms. Chin has no way of knowing which of these the government may offer in evidence against her. Examples include the following:

- a) Exhibits 4, 14, 15, 16, 17, 18, 19, 66, 67, 68, 75, 76, 77 and 78, some of which were not introduced in prior trials, contain hundreds of pages of orders and pharmacist verification forms for fourteen institutions, many of the which may have been signed by Kathy Chin (and others, i.e. Michelle Thomas, Alla Stepanets),
- b) Exhibits 135, 136, 137, 138, 139, 140, 157, 165, 221 , 222 , 223, 578, 583 and 584 all contain verification sheets or logged formula worksheet which may have been signed by Kathy Chin for shipments for which she is not charged,
- c) Exhibit 843 Logged Formula Worksheet,
- d) Exhibit 822 Pharmacist Verification Form (included among 16 pages),
- e) Exhibit 819 Pharmacist Verification Form and Logged Formula Worksheet (included among 35 pages),
- f) Exhibit 882 is a Barry Cadden email which has an attached Logged Formula Worksheet where Kathy Chin may be the verifying pharmacist.

## **ARGUMENT**

### **The thousands of uncharged shipments are inadmissible against Kathy Chin.**

Evidence of thousands of uncharged shipments is not admissible to prove the charges against Kathy Chin. Ms. Chin is charged in four separate counts with authorizing four individual shipments of drugs without valid prescriptions. She is not charged in any RICO or conspiracy count in this indictment. She is not charged in the Count Three Conspiracy to defraud the FDA.

Ms. Chin was a low level employee in the shipping department and had no supervisory role at the company. Thus she cannot be held vicariously liable for wrongdoing – if any – by the corporation or her coworkers.

Evidence concerning thousands of other uncharged shipments is irrelevant to the four counts that Kathy Chin faces in this indictment. The fact that some other shipments verified by Kathy Chin had what the government contends to be obviously fake patient names written on the Prescription Order Form is at best evidence of propensity not admissible in a trial of these charges. FRE 404(b). Indeed it is not even evidence of propensity as the government has no evidence that Kathy Chin ever saw or knew about any of the alleged fake names including in the four charged counts.

But more fundamentally, the evidence has no relevance at all given that it was not Kathy Chin's job to verify patient names in her role as checking pharmacist. Similarly, many of the uncharged shipments as to which the government intends to introduce evidence against Kathy Chin have nothing to do with patient names or prescriptions. Instead they apparently have to do with other alleged deficiencies in the NECC compounding process none of which were Kathy Chin's responsibilities or form part of any of the charges against her.

Kathy Chin cannot be held responsible for the actions of her coworkers and evidence of alleged wrongdoing by her codefendants is not admissible against her in this case. In this Kathy Chin is placed very differently from codefendants charged in RICO or conspiracy counts. It is entirely legal and appropriate for a pharmacist to work in a corporate setting. There is no requirement that all aspects of compounding or dispensing medications be completed by a single pharmacist. A pharmacist who is hired to perform a particular job is not responsible for aspects of the compounding or dispensing process performed by others at the company.



As this court recognized previously in this case, “Vicarious liability, whether vertical, or as the government would have it here, inverted, has no place in the criminal law as our Rules of Evidence recognize. “[T]hough in a civil suit, the principal may in some cases be answerable in damages to the party injured through the default of the deputy; yet, in a capital prosecution, the sole object of which is the punishment of the delinquent, each man must answer for his own acts or defaults.” Sir William Oldnall Russell, *A Treatise on Crimes and Indictable Misdemeanors*, Vol. I at 459 (2d ed. 1826).” *United States v Cadden et. al*, 14-cr-10363-RGS, “Memorandum and Order on Defendants’ Joint Motion to Exclude Evidence of Patient Harm Related to Methylprednisolone Acetate,” Document 1495, Filed 05/07/18, Page 16 of 17 ((footnote 10 omitted)).

The government acknowledges that the dispensing process at NECC was a distributed, multi-step, multi-employee process overseen by Barry Cadden. Government *Motion to Reconsider Dismissal of Charges Against Chin*, Docket # 692, p. 3. Nevertheless, the government claims that Kathy Chin was responsible for confirming that the orders had valid prescriptions (and apparently everything else that went on at the company) even though that was not her job because she was “the *only pharmacist*” to review the drug orders prior to shipment.” *Id.*, p. 1 and 4 ( emphasis in original).

There is, however, no such legal standard of liability. Even a senior corporate executive - which Kathy Chin was not – cannot be held responsible for corporate wrongdoing unless he had responsibility for and authority to direct the work. *United States v. Park*, 421 US 658, 673-674 (1975). (“[T]he Government establishes a prima facie case when it introduces evidence ... that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.”)(emphasis added). Even knowledge of wrongdoing will not subject a senior

executive to criminally responsible for the actions or inactions of another employee if the executive lacked the position, responsibility and authority to prevent or remedy the wrong.

The government does not allege that Kathy Chin was a senior executive responsible for confirming prescriptions or that she had authority to direct anyone in the confirming department much less less Barry Cadden. Lacking any legitimate applicable theory of criminal liability against Ms. Chin, the government has invented the “only pharmacist to see the order” doctrine. Unlike the carefully circumscribed liability of a senior executives set forth in *Park*, limited as it is by position, responsibility and authority, under the government's theory any pharmacist - no matter how lowly her position in the company or limited her job duties - would have unlimited liability for corporate wrongdoing in connection with compounding or dispensing drugs.

But the fact that one has a professional license does not alone create criminal liability for the wrongdoing of others in a corporate setting. If it did, no professional could work in a corporate setting or as other than a sole practitioner. The government does not allege that Kathy Chin ever failed to do her job, ensuring that the right drugs went to the right facility. On the contrary, Ms. Chin was good at her job; she was fast and accurate, regularly catching errors in the items she was responsible for checking – which did not include prescriptions or patient names. Ms. Chin never held any other position at NECC. The government does not allege that the drugs that were shipped pursuant to the four charged orders were tainted, improperly prepared or tested or caused harm to anyone at all.

It is not clear whether the government in claiming that the checking pharmacist was the “*only pharmacist*” (emphasis in original) to review the drugs prior to shipment is suggesting that NECC or the confirming department were criminally understaffed. But if so that was Barry Cadden's responsibility; Kathy Chin had neither position, responsibility or authority for hiring pharmacists at NECC. Kathy Chin had sufficient resources to do her job and did it well. She

cannot be held vicariously liable for deficiencies - if any – elsewhere in the company. Therefore, evidence of thousands of drug shipments other than those in the four counts charged against her is inadmissible.

**The summary exhibits are misleading as to Kathy Chin.**

Even if evidence of uncharged shipments were admissible against Kathy Chin, which it is not, the government summary exhibits would not be admissible in their current form.

Government Exhibit 595 purporting to contain a summary of patient name discrepancies is particularly misleading in calling out only the checking pharmacist who had no obligation for confirming prescriptions or patient names and failing to disclose the NECC confirming agent who did have that responsibility, the dispensing pharmacist Barry Cadden or the prescribing physician. The summary exhibit implies that the checking pharmacist, and only the checking pharmacist, had responsibility for confirming the presence of valid prescriptions for each shipment, which is simply not true.

Similarly, government summary exhibits 824 and 826 which suggests that Kathy Chin as checking pharmacist should have known or could have prevented the sale of contaminated Methylprednisolone or that she as the pharmacist who signed the logged formula worksheet had some responsibility for the licensing of pharmacy technicians at NECC are equally misleading. Those documents should be stricken or if the shipments are admissible against other defendants or on other charges at a minimum the column listing Kathy Chin's name should be removed.

**This massive number of additional shipments will delay the trial.**

Finally, if the government is allowed to offer evidence of these additional shipments, each one will require substantial additional pretrial preparation and trial time. The defendant will need to find and review the documents for each shipment, a herculean task in itself. For example, the defendant will likely dispute that the invoices in fact contain obviously fake patient names

and/or that she ever saw them in her work as checking pharmacist at NECC and she would need to review each Prescription Order Form to confirm that. As to other alleged deficiencies in the Compounding and dispensing process, the defendant would need to review the documents and try to understand how the process worked at NECC. For example, some LFWs apparently contain handwritten changes to expiration dates, which the government suggests were illegal. In fact it appears that many of these changes were appropriate corrections to the outdated information provided by the computer program. All of this, though completely irrelevant to the charges against Ms. Chin, would take substantial pretrial preparation and trial time.

### **CONCLUSION**

Wherefore, the defendant Kathy Chin moves for an order *in limine* excluding evidence of or reference in the arguments of counsel to any uncharged shipments of drugs against her in this case.

Alternatively, the defendant requests the court order the government to provide a list of exhibits and uncharged shipments it intends to offer against Kathy Chin, including those listed in summary exhibits with reference to underlying documents by Bates number, and that the court order a postponement of the trial as to Kathy Chin and severance from her codefendants to enable her prepare to defend against what are in effect thousands of new charges.

### **REQUEST FOR ORAL ARGUMENT**

Defendant believes that oral argument will assist the Court and requests a hearing on this motion. Local Rule 7.1(d).

Respectfully Submitted,

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By her attorney,

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Date: September 12, 2018

**CERTIFICATE OF SERVICE**

I hereby certify that the above document was served on all parties of record by ECF filing on September 12, 2018.

/s/ Joan M. Griffin  
Joan M. Griffin